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EXAMINER	
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GREGORY D FERRARO
CARELLA BYRNE BAIN GILFILLAN CECCHI
STEWART & OLSTEIN
6 BECKER FARM ROAD
ROSELAND NJ 07068

DATE MAILED: 11/29/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

for restriction only

A shortened statutory period for response to this action is set to expire 0 month(s), 30 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-20 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☐ Claims _____ are rejected.
5. ☐ Claims _____ are objected to.
6. ☒ Claims 1-20 are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, drawn to nucleic acid, classified in class 435, subclass 69.1.

II. Claims 8 and 9, drawn to polypeptide, classified in class 530, subclass 350.

III. Claim 10, drawn to an antibody, classified in class 530, subclass 387.1.

IV. Claim 11, drawn to a compound that activates the polypeptide of Group II, classified in class and subclass vary depending on what the compound is.

V. Claim 12, drawn to a compound that inhibits the polypeptide of Group II, classified in class and subclass vary depending on what the compound is.

VI. Claim 13, drawn to a method of treatment comprising administering the compound of Group IV to a patient, classified in class 514 or 424, subclass varies depending on what the compound is.

VII. Claim 14, drawn to a method of treatment comprising administering the compound of Group V to a patient, classified in class 514 or 424, subclass varies depending on the compound.

VIII. Claim 15, drawn to an *in vivo* method of using the compound of Group IV, classified in class 514, subclass 44.

IX. Claim 16, drawn to an *in vivo* method of using the compound of Group V, classified in class 514, subclass 44.

X. Claims 17 and 18, drawn to a method of identifying a compound which interacts with the polypeptide of Group II, classified in class 435, subclass 7.2.

XI. Claim 19, drawn to a method of diagnosing a disease using the nucleic acid of

Group I, classified in class 435, subclass 6.

XII. Claim 20, drawn to a method of detecting the presence of the polypeptide of Group II, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other for the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons:

Inventions I-V are directed to physically and functionally distinct products; therefore, they are patentably distinct inventions and are not required one for the other. The polypeptide of Group II can be prepared by materially different processes other than transcription and translation of its encoding nucleic acid, such as chemical synthesis or isolation and purification from its native source. The antibodies of Group III can be generated by immunizing animals with synthetic peptides instead of the full length polypeptide and can be used to isolate the protein. Additionally, the antibodies can serve as diagnostic agents in immunoassays and as therapeutic agents. In addition to expressing the polypeptide, the nucleic acid of Group I can be used as a probe for localizing the expression of the encoding polypeptide in various tissues or as a therapeutic agent in gene therapy. The activator of Group IV and the inhibitor of Group V are useful as agents for regulating the activity of the receptor of Group II. They are structurally distinct from the nucleic acid, the polypeptide and the antibodies of Groups I-III.

In a similar manner, the above statement regarding "Relationship of Inventions" is applicable to multiple methods.

Inventions VI-XII are directed to different methods of using the products of Inventions I-V; thus, they are patentably distinct inventions and are not required one for the other. The methods of Inventions VI-XII require different starting material and different method steps and are directed to the achievement of different goals.

Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as to enhance the activity of the polypeptide in an *in vitro* cell assay.

The method of Invention VI does not require the products of Inventions I-III and V.

Inventions V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as to inhibit the activity of the polypeptide in an *in vitro* cell assay.

The method of Invention VII does not require the products of Inventions I-IV.

Inventions VIII and IX require the nucleic acid encoding the products of Inventions IV

and V, respectively, and do not require the products of Inventions I-V.

Inventions I and X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process such as to express large quantities of the protein.

Inventions I and XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different method such as to express large quantities of the polypeptide.

Inventions III and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different method such as to isolate the polypeptide.

Because these inventions are distinct for the reasons given above and have acquired a

separate status in the art as shown by their different classification and their divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to attorney Jay Mullins on November 15, 1996, to request an oral election to the above restriction requirement, but did not result in an election being made. The attorney specifically requested a written restriction.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication should be directed to Sally Teng, Ph.D., at telephone number (703)308-4230. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Walsh, can be reached at telephone number (703)308-2957.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703)308-0294.

Sally P. Teng
November 25, 1996

SALLY TENG
PATENT EXAMINER
GROUP 1800